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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,152	02/11/2002	Christopher A. Barker	9001-0042.01	8156

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EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/074,152	BARKER ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-147* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-147* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-32, 50-52, 54-56, 58-60, 62-64, 66-68, 70-72, drawn to myostatin peptide, myostatin immunoconjugate, vaccine composition classified in class 530, subclass 387.1.

II. Claims 32-49, 53, 57, 61, 65, 69, 73, drawn to myostatin multimer, myostatin multimer immunoconjugate and vaccine composition classified in class 530, subclass 387.1.

III. Claims 74-76, 78-80, 82-84, 86-88, 90-92, 94-96, 98, 99, 101, 102, drawn to a method of eliciting an immune response comprising administering a myostatin peptide, classified in class 514, subclass 2.

IV. Claims 77, 81, 85, 89, 93, 97, 100, 103, drawn to a method of eliciting an immune response comprising administering a myostatin multimer classified in class 514, subclass 2.

V. Claims 104-106, 108-113, 115-120, 122-125, 128, drawn to a polynucleotide encoding a myostatin peptide, vector, host cell, method of making myostatin peptide, classified in class 435, subclass 69.1.

VI. Claims 107, 114, 121, 126, 127, 129-131, drawn to a polynucleotide encoding a myostatin multimer, vector, host cell, method of making myostatin multimer, classified in class 435, subclass 69.1.

VII. Claims 132, 133, 135-138, 140-143, 145, 146, drawn to a method of eliciting an immune response comprising administering a polynucleotide encoding a myostatin peptide, classified in class 514, subclass 44.

VIII. Claims 134, 139, 144, drawn to a method of eliciting an immune response comprising administering a polynucleotide encoding a myostatin multimer, classified in class 514, subclass 44.

IX. Claim 147, drawn to antibody, classified in class 424, subclass 134.1.

Inventions I, II, V, VI, IX are patentably distinct products.

The polypeptides of Groups I/II and the polynucleotides of Groups V/VI are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. A nucleic acid, even when hybridizing under stringent conditions, can encompasses molecules which contain point mutations, splice sites, frameshift mutations or stop codons. This results in use of a different open reading frame, and thus encodes a protein that lacks any significant structure in common with myostatin. Groups I, II and V, VI have a separate status in the art as shown by their different classifications.

The multimers of Groups II/VI and the monomers of Groups I/V are patentably distinct inventions for the following reasons. The multimer products are distinct both physically and functionally. Multimers have significant three-dimensional structure differences which affect spatial orientation of binding and active sites, function and activity and thus are therefore patentably distinct from monomer products.

The polynucleotides of Groups V/VI and the antibody of Group IX are patentably distinct for the following reasons. The antibody of Group IX includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs). Polypeptides, such as the antibody of Group IX which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, the polynucleotides of Groups V and VI will not encode an antibody of Group IX, and the antibody of Group IX cannot be encoded by the polynucleotides of Groups V and VI. Therefore the antibody and polynucleotide are patentably distinct. Furthermore, searching the inventions would impose a serious search burden since a search of the polynucleotides of Groups V and VI would not be used to determine the patentability of an antibody of Group IX, and vice-versa.

The polypeptides of Groups I/II and the antibody of Group IX are patentably distinct for the following reasons. The polypeptide and the antibody of are structurally distinct molecules. Any relationship between a polypeptide and an antibody is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide. In this case, the polypeptides of Groups I and II are large molecules which contains potentially hundreds of regions to which an antibody may bind, whereas the antibody of Group IX is defined in terms of its binding specificity to a small structure within myostatin. Therefore the polypeptide and antibody are patentably distinct. The inventions have a separate status in the art as shown by their different classifications. In addition, the technical literature search for the polypeptide and the antibody are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

Inventions I, II, V, VI, IX and III, IV, VII, VIII, are unrelated products and processes. Inventions I (product) and IV, VII, VIII (process); II (product) and III, VII, VIII (process); V (product) and III, IV, VIII (process); VI (product) and III, IV, VII (process), IX (product) and III, IV, VII and VIII (process) are unrelated because the product is not used or otherwise involved in the process.

Inventions III, IV, VII, and VIII are unrelated processes. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Each invention performs its function using a structurally and

functionally divergent material. Furthermore, a method of administering a polypeptide and a method of administering a polynucleotide would have a separate status in the art as shown by their different classifications.

Inventions I (product)/III (process), II (product)/IV (process), V (product)/ VII (process); VI (product)/VIII (process) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide product can be used to make antibodies as opposed to its use in a method of eliciting an immune response. The polynucleotide product can be used to make recombinant proteins as opposed to its use in a method of eliciting an immune response. Searching the inventions would impose serious search burden, as the inventions of Groups I/III, II/IV, V/VII, VI/VIII have a separate status in the art as shown by their different classifications.

The Examiner has required restriction between product and process claims. Where Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of**

the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

RMD
9/27/04